Evidential Use of Diagnostic Ethanol Test Findings
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Hospital laboratory (diagnostic) ethanol testing is intended to provide health care professionals with information sufficient to avoid treatment which could adversely impact a patient who has ingested ethanol. While diagnostic test results may be sufficient for therapeutic use, it is not the mission of the laboratory to provide results that necessarily meet evidential standards[1]. With treatment guidance being the intended use, the value of diagnostic test results ends with a positive patient outcome, which largely renders test result accuracy and reliability moot. Because evidential test results are intended to remain forever insight into past occurrences, its value has no finite lifespan so there is nothing to render accuracy and reliability moot.

Evidential testing may incorporate the same or different methodology as diagnostic testing to derive the same or similar result(s). However, because evidential testing is intended to provide a legally defensible work product, evidential testing incorporates practices and documentation considering such intended use.

Evidential specimens must be collected, identified, sealed, transported and maintained such that the condition, as is practical, will not change prior to analysis in a manner that could impact the relevant analysis or target analyte(s). Evidential analyses must be conducted pursuant to approved, validated methods and incorporate sufficient quality assurance practices to ensure accuracy and reliability of any results. Laboratory analysts must be qualified and authorized to conduct analyses. Evidential results must then be interpreted properly in order to answer a question within the context of the situation at hand, typically to assess human performance during some criminal or other activity.

Evidential testing is purposely conducted in a manner that supports examination in Court and analysts are prepared to testify to prove its accuracy and reliability. This is not to exclude diagnostic testing that is deemed accurate and reliable. While diagnostic testing is not subject to the same degree of examination when results are applied to the intended therapeutic use, diagnostic testing and analysts should be examined when results are applied to an unintended evidential use. Should examination reveal that diagnostic testing is conducted with practices, personnel and specimens that satisfy the Court, then results may be deemed sufficient for evidential use.

One must also distinguish ANALYSIS and INTERPRETATION when examining toxicological evidence because factors may have bearing on one process but not the other. For example, Court examination may focus on “chain of custody”. Chain of custody *per se* is not *the* issue in a forensic examination, rather assurance that the evidence does not change, or otherwise does so only in a predictable manner during the period between collection and analysis. This includes tamper-evident sealing and proper maintenance. Chain of custody only directly addresses the “who” and “where”. Even then, evidence changes may not preclude analysis but may significantly impact interpretation of the findings.

[1] Frye v. U.S., 293 F. 1013 (D.C. Cir 1923); Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993); Kumho Tire v. Carmichael 526 U.S. 137 (1998)

The following listed issues have been examined during my experience in Court. This list is not exhaustive nor do individual items bear equal significance. Some may overlap or be otherwise redundant. General areas of examination include the following.

Specimen collection, maintenance and transportation to the laboratory

Specimen preparation

Apparatus calibration

Apparatus and analysis quality assurance

Specimen analysis

Laboratory quality assurance

1. Is there a record of who collected the specimen? If not, is it otherwise known who collected the specimen?
2. Was the phlebotomist qualified and authorized to collect the specimen?
3. Did the phlebotomist prepare the collection site with an "alcohol-free" cleansing procedure?
4. Did the phlebotomist collect the specimen in a manner to avoid contamination with microorganisms that could adversely affect the specimen (aseptic technique)?
5. Did the phlebotomist collect the specimen pursuant to an approved policy?
6. Did the subject receive fluids via intravenous infusion during treatment prior to specimen collection?
7. If so, was the specimen collected from the same or opposite limb as the point of infusion?
8. Did the phlebotomist collect the specimen with approved collection apparatus and tube?
9. What type of collection tube was used (tube pre-collection contents, stopper color, etc.)?
10. Was the collected specimen identified so as to distinguish it from specimens collected from other subjects?
11. Was the specimen collection container sealed to prevent loss of specimen or contamination with specimens collected from other subjects?
12. Was the collected specimen transported to the laboratory in a secure and timely manner?
13. Is there a record of who transported the specimen to the laboratory and when? If not, is it otherwise known who transported the specimen to the laboratory and when?

14. Is there a record of who received the specimen in the laboratory and when? If not, is it otherwise known who received the specimen in the laboratory and when?
15. Was the collected specimen maintained in a manner that could permit degradation or decomposition during the period prior to analysis?
16. Is there a record of who prepared the specimen for analysis? If not, is it otherwise known who prepared the specimen for analysis?
17. Was the individual who prepared the specimen for analysis qualified and authorized to do so?
18. Did the individual prepare the specimen for analysis pursuant to approved policy?
19. How did the individual prepare the specimen for analysis?
20. What was the final specimen matrix intended for analysis?
21. Is there a record of who analyzed the specimen and when? If not, is it otherwise known who analyzed the specimen and when?
22. Was the individual who analyzed the specimen qualified and authorized to do so?
23. Did the individual analyze the specimen pursuant to approved policy?
24. How did the individual analyze the specimen?
25. What apparatus was used to analyze the specimen?
26. Was the apparatus calibrated?
27. What is the frequency of calibration?
28. What is the concentration range for calibration?
29. Was the apparatus calibrated pursuant to approved policy?
30. Were proper reagent lots used to complete the calibration?
31. Were calibration analysis reagent lots expired?
32. Were calibration materials themselves expired?
33. Were control materials used to verify accuracy of the analysis?
34. What is the frequency of control analysis?
35. What control concentrations were used?
36. Were control materials analyzed pursuant to approved policy?
37. Were proper reagent lots used to analyze controls?
38. Were control analysis reagent lots expired?
39. Were control materials themselves expired?

40. What are the approved quality assurance acceptance criteria for the results of control materials?
41. Did the results of controls meet approved quality assurance acceptance criteria?
42. Were proper reagent lots used to analyze the specimen?
43. Were specimen analysis reagent lots expired?
44. Did the reported specimen test result fall within the calibration range of the apparatus?
45. Is there any indication that the apparatus was functioning in an inaccurate or unreliable manner?
46. Is there any indication that the intended specimen was not analyzed?
47. Is there any indication that the reported test result applied to a specimen other than the intended specimen?
48. Is there any indication that the apparatus reported inaccurate or unreliable test results for the specimen?
49. Is there information available regarding the ability of substances other than ethanol to be recorded as a positive finding for ethanol?
50. Is the laboratory accredited to conduct analyses? If so, please describe.
51. Does the laboratory have an external quality assurance monitoring program? If so, what is the frequency of challenges?
52. If the laboratory has an external quality assurance monitoring program, were the results of the relevant external proficiency sample analyses satisfactory before and after the analysis of the subject specimen? If not, what was the basis for non-satisfactory results?